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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/600,500	11/15/2000	Anthony John Fist	J&J-1763	4831

7590 05/19/2004
Audley A Ciamporcero Jr
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003

EXAMINER

HWU, JUNE

ART UNIT	PAPER NUMBER
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1661

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/600,500	FIST ET AL.	
	Examiner	Art Unit	
	June Hwu	1661	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23,38,46 and 50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23,38,46 and 50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/8/01 & 5/7/01</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Applicants' election of Group I, claims 1-23, 38, 46 and 50 dated August 23, 2002 is acknowledged. The election has been treated as an election without traverse because Applicants have not noted otherwise.

Objections to the Specification

The disclosure is objected to because of the following informalities: The flow charts on pages 2, 14, 16, and 20 must be deleted or presented as a drawing. See 37 CFR 1.58(a). Appropriate correction is required.

On page 11, the address to the American Type Culture Collection is in correct and should be changed to the address in Manassas, Virginia. Correction is necessary.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Claims 1-23, 38, 46, and 50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention employs *Papaver somniferum* seeds of mutagenized plants. Since the seeds are essential to the claimed invention they must be obtainable by a repeatable method

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set forth in the specification or otherwise be readily available to the public. Under natural variation, not all poppy seeds are the same. If they are not so obtainable or available, the requirements of 35 U.S.C. § 112, regarding "how to make" the invention may be satisfied by deposit. For the plant, a deposit of 2500 seeds is considered adequate to ensure availability of each claimed embodiment. The specification does not disclose a repeatable process to obtain the seeds, because it appears only one experiment was performed in which the trait with high (S)-reticuline was observed (page 18). The specification does not disclose the accession number for the deposit and the date of the deposit. If the deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific plant line has been deposited under the Budapest Treaty and that it will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit is not made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and,

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(d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and,

(e) the deposit will be replaced if it should ever become inviable.

Once the deposit is perfected, the specification would be enabling only for the deposited seeds and plants grown therefrom.

Enablement is considered in view of the *Wands* factors (MPEP 2164.01(a)).

Nature of the invention. The claims are drawn to biological material, specifically a *Papaver somniferum* with higher content of (S)-reticuline than morphine and method of making said plant.

Breadth of the claims. The claims are broad, encompassing any *Papaver somniferum* with higher reticuline content. The claims are not limited to a specific trait found after treating seeds with ethyl methanesulphonate.

State of the prior art. No prior art teaches how to modify poppy plants to obtain high reticuline over morphine content.

Predictability of the art. Genetic variability in determining the alkaloid content in poppy is generally unpredictable. The specification does not disclose what starting material was used. Singh has shown that five cultivars of poppy showed different morphine contents (Table 1). Singh has shown that M₃ poppy plants have a range of variability in morphine content from 8.07 to 20.66% (page 381). Given the natural variation observed in the species, combined with the random nature of mutagenesis, one cannot predict whether the results disclosed in the specification would be reproducible.

Guidance in the specification. The specification does not provide any guidance as to how to obtain plants from genetic engineering because no gene sequences are disclosed. The

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specification does not show any guidance on how to produce plant in which certain specific enzymes are inhibited. Only the mutagenic process is disclosed in detail.

Existence of working examples. There are no working examples on how to inhibit enzymes. There are no working examples for an alternative way of producing high reticuline through genetic engineering. A working example is provided only for the mutagenic process.

Amount of experimentation necessary. The amount of experimentation would be high given the unpredictability of obtaining different strains of poppy with specific reticuline and morphine ratios as claimed.

For the reasons discussed above, it would require undue experimentation for one skilled in the art to make and use the claimed invention.

Written Description

Claims 1-23 and 38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-23 and 38 are drawn to *Papaver somniferum* plants having a higher trait of (S)-reticuline over morphine content. The specification only describes deposited seeds of mutagenized plants of *Papaver somniferum* (page 10-11). Claims 4-7 are drawn to a *Papaver somniferum* in which the production or activity of enzymes are inhibited. The specification does not provide any information as to how these enzymes are inhibited, how to target these enzymes, or how to assay for activity of these enzymes. There is no evidence that the deposited plants are deficient in the activity of any of the recited enzymes.

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In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been described by their complete structure. It is not realistic to expect that the "complete structure" of the poppy plant could be described. Therefore, the inquiry required by this portion of the written description guidelines is interpreted to be whether all genetic variability of the poppy has been described. In this case, the few disclosed embodiments are not representative of the enormous number of products claimed. The claims encompass *Papaver* varying in all possible phenotypic characteristics such as flower size, capsule size, etc.

Next, then, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics. It is not possible to adequately describe the claimed products because only the deposit is disclosed. The limited disclosure in the specification is not deemed sufficient to reasonably convey to one skilled in the art that Applicants were in possession of the genera recited in the claims at the time the application was filed. Thus it is concluded that the written description requirement is not satisfied for the claimed genera.

Limiting the claims to the deposited material and progenies thereof having the high (S)-reticuline in comparison to morphine could overcome the rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-23, 38, 46 and 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically:

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Claims 1-23 are indefinite in their recitation of "selected" because it is unclear what the selection process entails.

The term "stably reproducing" in claims 1-23, 38, 46 and 50 is a relative term, which renders the claim indefinite. "Stability" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention.

Claim 4 is grammatically incorrect and indefinite because it is missing a verb.

Claims 10 and 17 are indefinite in their recitation of "100% or greater by weight" because ratios are not expressed as percentages, and they do not have units of measurement.

Claims 11 and 18 are indefinite in their recitation of "200% or greater by weight" because ratios are not expressed as percentages, and they do not have units of measurement.

Claims 12 and 19 are indefinite in their recitation of "1250% or greater by weight" because ratios are not expressed as percentages, and they do not have units of measurement.

Claims 13 and 20 are indefinite in their recitation of "2500% or greater by weight" because ratios are not expressed as percentages, and they do not have units of measurement.

Claim 38 is unclear in its recitation of "stand" because it is uncertain if this encompasses just plants or the whole field including weeds, insects, etc.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 38 is rejected under 35 U.S.C. 101 because the term "stand" of plants is essentially a field of plants. This would include weeds, grass, etc., which are a product of nature. Therefore, the claim encompasses non-statutory subject matter.

References Cited

The Crane reference is cited but not applied in any rejection herein are made of record to show the state of the art, and are the most similar to the instant application known to the Examiner. Crane et al discloses the alkaloid contents in seedlings of *Papaver somniferum* in which it appears that there is a larger spot of reticuline over morphine on day 4 (Figure 2 and page 90). However, Crane et al speculates that this is true but is not positive.

In the restriction dated December 3, 2001, the previous Examiner cited the Symanowska reference. However, after reviewing the Symanowska reference there is no anticipation. The Symanowska reference does not mention a higher reticuline over morphine content.

Conclusion

Claims 1-23, 38, 46 and 50 are not allowed. The claims are free of prior art because there are no references that taught or suggested *Papaver somniferum* having a trait with higher (S)-reticuline than morphine content.

Foreign Priority

Acknowledgment is made of applicants' claim for foreign priority based on an application filed in Australia on January 14, 1998.

Future Correspondence

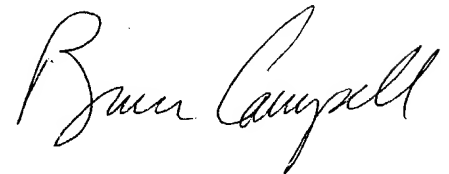
Any inquiry concerning this communication or earlier communications from the examiner should be directed to June Hwu whose telephone number is (571) 272-0977. The Examiner can normally be reached Monday through Thursday from 6:30 a.m. to 5:00 p.m.

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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The fax number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JH

A handwritten signature in cursive script, reading "Bruce Campell".

**BRUCE R. CAMPPELL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600**